

**MULTI-SYMPTOM MAPAP COLD FORMULA- acetaminophen,
dextromethorphan hbr, phenylephrine hcl tablet**
Major Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Major 44-470C-CMS

Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - nasal congestion
 - headache
 - cough
 - sinus congestion and pressure
 - sore throat
- helps clear nasal passages
- promotes nasal and sinus drainage
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash

- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- liver disease
- heart disease
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- diabetes
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed**
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - swallow whole - do not crush, chew, or dissolve
 - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 0904-5786-24

Compare to active ingredients in Tylenol® COLD MAX*

MULTI-SYMPTOM

Mapap®

COLD FORMULA

CAPLETS

ACETAMINOPHEN

DEXTROMETHORPHAN HBr

PHENYLEPHRINE HCl

Pain Reliever / Fever Reducer

Cough Suppressant • Nasal Decongestant

For Relief of: Fever, Headache,
Sore Throat, Nasal Congestion, Coughing

DAYTIME • NON-DROWSY
ASPIRIN FREE

24 CAPLETS with Cool Blast Flavor

Actual Size

*This product is not manufactured or distributed by Johnson & Johnson Corporation,
owner of the registered trademark Tylenol® COLD MAX.

50844 REV0718F47008

Distributed by **MAJOR® PHARMACEUTICALS**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA M-17 Rev. 08/18

Re-order No. 006363

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

No print area
Lot no. & Exp. Date



Drug Facts (continued)
sucralose, talc, titanium dioxide
Questions or comments? (800) 616-2471

Drug Facts
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(in each caplet)
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MAJOR®

NDC 0904-5786-24
Compare to active ingredients
in Tylenol® COLD MAX*

MULTI-SYMPTOM Māpap® COLD FORMULA CAPLETS

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B-1212-470C-08-CMS
REV0718F47008

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■ If you have ever had an allergic reaction to this product or any of its ingredients
■ Ask a doctor before use if you have:
■ thyroid disease
■ high blood pressure

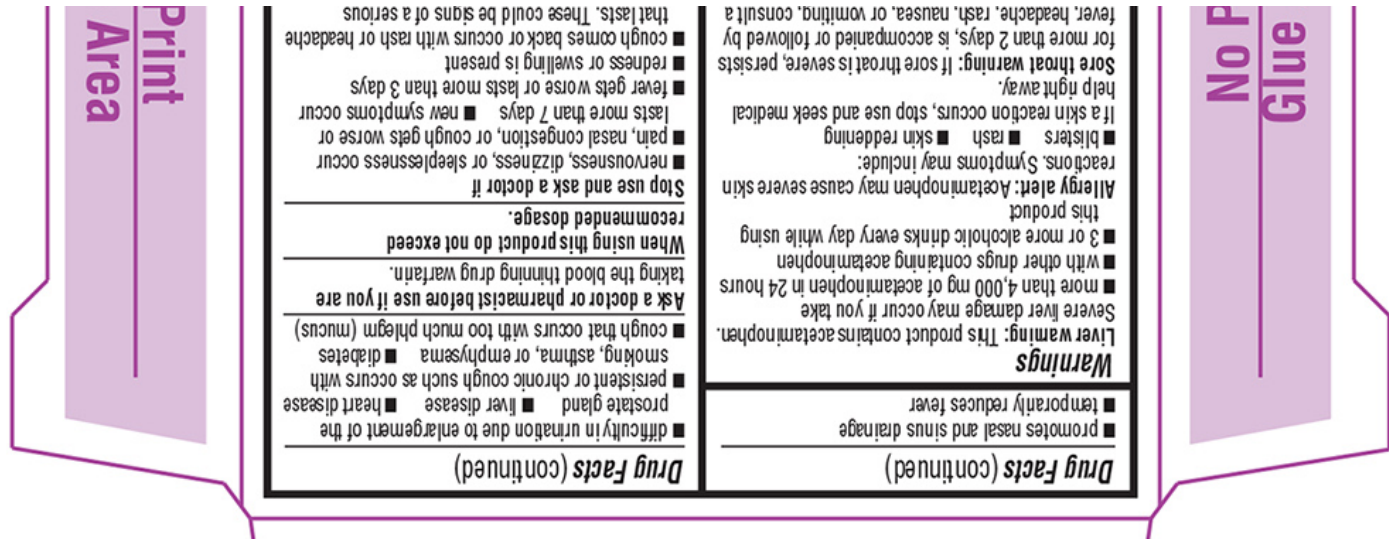
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No 1
Glue

Print
Area



Major 44-470C

MULTI-SYMPTOM MAPAP COLD FORMULA

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5786
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg
Inactive Ingredients			
Ingredient Name			Strength
STARCH, CORN (UNII: O8232NY3SJ)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor	MINT	Imprint Code	44;470
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5786-24	2 in 1 CARTON	07/15/2005	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/15/2005	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-5786)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(0904-5786)

Revised: 3/2021

Major Pharmaceuticals